REMARKS

Claims 1-7, 9-23, 26 and 28-30 are pending and rejected. Claims 1 and 2 are amended for grammar. Applicant respectfully requests reconsideration for the following reasons.

CLAIM REJECTIONS UNDER 35 U.S.C. §103

Claims 1-7, 9-23, 26 and 28-30 are rejected under 35 U.S.C. §103(a) as obvious over Hoffman in view of Ghosal and Petrus. Applicant respectfully disagrees.

Applicant's claims require Vitamin C within specified concentration ranges, as well as Vitamin E, and at least one stabilizing agent.

> A composition comprising an ocular solution containing
>
> Vitamin C and
>
> Vitamin E and
>
> at least one stabilizing agent in an amount effective to stabilize the solution against oxidation
>
> wherein the concentration of Vitamin C is about 1% to about 25% of the ocular solution within the limits of solubility or
>
> the concentration of Vitamin C is from about 0.01% to about 0.03% of the ocular solution.

Applicant respectfully disagrees that Hoffman in view of Ghosal and Petrus render the composition obvious.

Hoffman's composition contains a plurality of antioxidants. If Hoffman's composition includes Vitamin C, the Vitamin C concentration ranges from about 0.05 wt % to 0.2 wt %, with a preferred Vitamin C concentration of 0.1 wt % (col. 3 lines 1-5).

Applicant's composition requires specific vitamin C concentrations outside of Hoffman's ranges. At Applicant's higher concentration range of about 1% to about 25% of the ocular solution, Applicant recognized that solubility may be a factor and thus limits the Vitamin C concentration to that "within the limits of solubility". Hoffman does not teach, suggest or motivate this recognition, because Hoffman's concentration is low and thus avoids any problem with solubility. At Applicants' lower concentration range of about 0.01% to about 0.03% of the ocular solution, the composition still provides anti-oxidant properties.

A person of ordinary skill in the art would not be taught by Hoffman that concentrations outside of Hoffman's range would be useful. A person of ordinary skill in the art would not be taught by Hoffman that at least one stabilizing agent for Vitamin C and Vitamin E is required in order to stabilize the composition against oxidation (i.e., deterioration). As Applicant has disclosed:

> Ocular solutions containing an antioxidant provide beneficial properties, for example, the antioxidant scavenges free radicals in the solution which may cause the solution to deteriorate. However, antioxidants are themselves extremely susceptible to oxidation. A stabilizing agent for the antioxidant retards or prevent the antioxidant from undesirable reactions and thus

> enhances its ability to stabilize the ocular solution. This in turn enhances the physiological properties of the ocular solution, which may be a topical solution such as eye drops, or a surgical ocular irrigation or volume replacement solution (p. 2 lines 15-23).

The Examiner asserts that Hoffman, the primary reference, teaches the use of glutathione in combination with Vitamin C and Vitamin E in an ophthalmic formulation but differs from Applicants' composition in that Applicant teaches the use of "propylene glycol, cysteine as a stabilizing agent and additives such as silicone and selenium." However, Hoffman does not teach, disclose, or suggest that if Vitamin C and Vitamin E are included in the solution, a stabilizing agent for these compounds must also be included, in order to prevent free radical formation in the solution that may cause the solution to deteriorate.

The Examiner states that it would be obvious to combine the teachings of Ghosal and Petrus with Hoffman, "since one relates to the use of the combination of glutathione, Vitamin C and Vitamin E at the claimed concentrations in an ophthalmic formulation, and the others relate to the use of propylene glycol, cysteine and additives such as silicone and selenium in combination with vitamins in ophthalmic formulation as old and well known."

The Examiner relies on Ghosal for teaching "the use of Vitamin C in combination with *Emblica officinalis* fruit extract and propylene glycol in a pharmaceutical formulation." Applicant previously canceled claim 8 reciting *Emblica officinalis*. In addition, Ghosal is not properly combined with Hoffman, at least because Ghosal teaches a moisturizing skin care gel containing propylene glycol (Example 20), thus teaching away from Applicant's composition of an ocular solution. One of ordinary skill in the art would not combine Hoffman's ocular solution with Ghosal's skin solution, at least because of organ differences: a composition applied topically to the skin must penetrate the barrier layers for efficacy, while a composition applied topically to the eye is simply taken up by a lubricated mucous membrane. Toxicity and pharmacokinetics (absorption, distribution, biotransformation, elimination) differ between agents applied to skin versus eye.

The Examiner asserts that Petrus teaches an ophthalmic formulation containing cysteine derivatives, silicone and selenium in combination with ascorbic acid and glutathione. As Applicant stated in his July 11, 2006 Amendment, Petrus is directed to a composition that penetrates the skin of the eyelid and uses a skin penetration enhancer (col. 2 lines 22-34; col. 4, lines 54-62). The enhancer increases skin permeability by "altering the physiochemical nature of the stratum corneum to reduce its diffusional resistance" (col. 4 lines 54-61). Petrus contain ingredients "that prepare the epidermis of the skin to receive bio-affecting agents" (col. 5 lines 54-56). Petrus teaches away from an solution that is administered into the eye itself because Petrus is directed to creams or gels applied to the skin, that is, the lid of the eye, not the surface of the eye (Example 1 and 2). Further, Petrus does not disclose, teach, or suggest an ocular solution

containing Vitamin C or Vitamin E and at least one stabilizing agent to stabilize the solution against oxidation. Accordingly, Petrus does not cure Hoffman's deficiency.

For at least these reasons, Applicant asserts that Hoffman in view of Ghosal and Petrus do not teach, suggest, or motivate Applicant's composition, and that the claims are allowable.

CONCLUSION

The application is believed to be in condition for allowance. No fees are believed due but, if deemed necessary, the Office is authorized to charge them to Deposit Account No. 20-0809. The Examiner is invited to contact Applicant's undersigned representative with questions.

Respectfully submitted,

/Beverly A. Lyman/

Beverly A. Lyman, Ph.D.
Reg. No. 41,961

Thompson Hine LLP
312 Walnut Street
14th Floor
Cincinnati OH 45202
Direct Dial 513 352 6596

662902